EXHIBIT 4

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Olmesartan-associated sprue-like enteropathy: a systematic review with emphasis on histopathology☆

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Summary Sprue-like enteropathy associated with the angiotensin II receptor blocker (ARB) olmesartan was first described in 2012, and a number of cases have since been reported. This syndrome is characterized by severe diarrhea and sprue-like histopathologic findings in the intestine, often with increased subepithelial collagen. The incidence of this adverse drug reaction is not entirely clear, although it is thought to be rare. It is also not well established if other ARBs cause such a syndrome, although case reports suggest they can. The histopathologic features of olmesartan-related injury have only been described in a limited number of cases, and there are no guidelines regarding the histopathologic distinction of olmesartan-associated enteropathy from other causes of sprue (eg, celiac disease, tropical sprue). Herein, we review the histopathologic changes and clinical observations described in recent reports of olmesartan-associated sprue-like enteropathy comprising case series and isolated reports, other relevant literature, and our experience at a referral center specializing in small intestinal disorders. We will review recent literature suggesting other ARBs can be associated with a similar phenotype. Lastly, we will discuss the histopathologic differential diagnosis and provide clues to distinguish this entity from other entities which can cause sprue-like histopathology.

1. Introduction

Olmesartan medoxomil is an antihypertensive drug, which acts by blocking the angiotensin II receptor. An association between olmesartan use and a severe sprue-like enteropathy was first described by Rubio-Tapia et al in 2012 [1]. A recent study has suggested that olmesartan use may also be associated with less severe histopathologic findings

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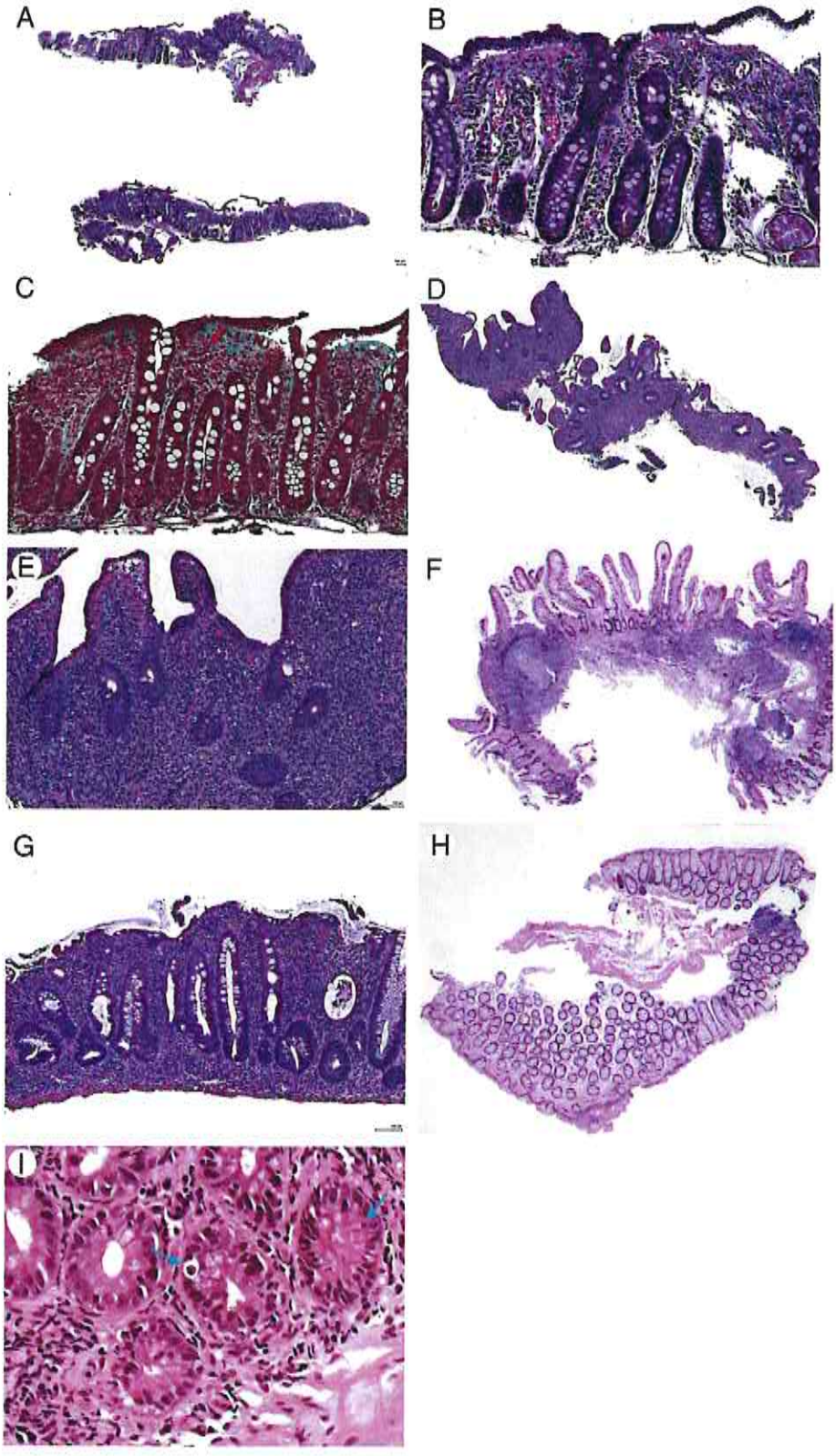
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in patients presenting with abdominal pain [2]. Case reports of patients taking other angiotensin receptor blockers and demonstrating a profound sprue-like enteropathy also exist [3-6]. The pathophysiology of olmesartan-associated enteropathy is somewhat unclear. However, a recent study proposed roles for IL-15 signaling and disruption of the tight junction protein ZO-1 in disease pathogenesis and showed an overlap between the changes observed in olmesartan enteropathy patients and active and refractory celiac disease patients [7]. Another study demonstrated similar clinical and histologic phenotypes between olmesartan enteropathy patients and autoimmune enteropathy (AIE) patients, suggesting immune dysregulation in the pathogenesis of this entity [8]. Awareness of the spectrum of clinical and histopathologic changes associated with olmesartan use is of great importance to practicing pathologists, as it will avoid misclassification of patients with other disorders and allow for a very simple but powerful intervention (namely, switching antihypertensive medication). This review examines case series, case reports, and other literature relevant to this topic and offers useful clues that may be helpful to pathologists considering olmesartan-associated injury as the etiology of small intestinal mucosal histopathology.

Rubio-Tapia et al [1] reported a series of 22 patients from the Mayo Clinic who presented with severe diarrhea and profound weight loss and uncovered the association between olmesartan exposure and a severe enteropathy. The time of symptom onset varied from several months to several years after commencement of the antihypertensive medication. Serologic testing for celiac disease was negative in all cases, and no patient responded to a gluten-free diet. Small intestinal biopsies showed villous atrophy, with 15 showing total villous atrophy. Fourteen also had a concomitant increase in intraepithelial lymphocytes (IELs), whereas 8 had a normal density of IELs. Of note, 7 patients had features of collagenous sprue (Fig. A-C). In 2010, the same group had noted that olmesartan use was present in one-third of a cohort of patients with collagenous sprue [9]. Of the 14 patients who also had gastric biopsies performed, 5 (36%) exhibited lymphocytic gastritis, and 2 (14%) displayed features of collagenous gastritis. Colon biopsies of 5 (38%) of the 13 patients showed microscopic colitis (2 lymphocytic, 3 collagenous). Clinical symptoms resolved quickly after cessation of the medications in all cases, and the histologic changes disappeared in the vast majority (17 of 18 patients with follow-up biopsy) [1]. These findings along with those from the case series discussed below are summarized in Table 1. A study performed at our institution evaluated a series of 72 patients with seronegative villous atrophy who had been referred for management of poorly responsive celiac disease. Although 20 patients (28%) had celiac disease–associated genotypes and responded to a gluten-free diet (seronegative celiac disease), 16 patients (22%) were found to be taking olmesartan, and these patients had similar clinical and histologic findings as described in the Mayo Clinic study, making olmesartan enteropathy the second most common etiology of seronegative villous atrophy. Of these 16 patients, 11 (69%) had collagenous sprue [10]. A study of nonceliac villous atrophy cases published before the description of olmesartan-associated enteropathy described unclassifiable immune mediated enteropathy as the etiology of 10 (33%) of 30 patients with nonceliac villous atrophy, with 3 (10%) considered to have "primary" collagenous sprue [11]. It is unclear whether a proportion of these cases were receiving or were exposed to olmesartan.

A smaller series (5 cases) of suspected olmesartan-related enteropathy was reported by a group in France. These patients had similar clinical and pathologic findings as described by Rubio-Tapia et al [1]. Two of the patients were rechallenged with olmesartan, and diarrhea recurred in both. The authors noted that theirs is a small gastroenterology service (4 gastroenterologists), so they wondered if this may be more common than currently thought [12]. Another study from France discussed 7 patients with severe enteropathy refractory to a gluten-free diet. Discontinuation of olmesartan did not lead to clinical resolution in 2 patients. However, remission was achieved with anti–tumor necrosis factor α therapy, suggesting that olmesartan may provoke an immune-mediated enteropathy [8]. A study from India described 7 patients who presented with watery diarrhea after taking olmesartan. The symptoms were severe enough to necessitate hospitalization of 3 patients. Duodenal biopsy showed total villous atrophy in 3 patients and partial villous atrophy in the remaining 4. Increased IELs were noted in all cases. Within a few days of discontinuing olmesartan, all 7 patients showed a marked improvement of their clinical symptoms. Repeat duodenal biopsies performed in 2 patients

Fig. Characteristic and unusual changes seen in ARB enteropathy. A, Two well-oriented duodenal biopsy pieces from an olmesartan-exposed patient show total villous atrophy and crypt hyperplasia (hematoxylin and eosin, original magnification ×4). B, Higher power view shows no significant intraepithelial lymphocytosis and suggests increased subepithelial collagen (hematoxylin and eosin, ×20). C, Trichrome stain confirms the increase in subepithelial collagen (Masson trichrome, ×20). D, Low-power view of an ileal biopsy from another ARB-exposed patient shows distorted villi, significant inflammation in lamina propria, and extensive crypt dropout (hematoxylin and eosin, ×4). E, Higher power view shows loss of both goblet and Paneth cells (hematoxylin and eosin, ×20). This biopsy was taken before the association between ARB and enteropathy was described, and the working diagnosis was autoimmune enteropathy. F, However, after several months off ARB, the ileum had reverted to normal histology (hematoxylin and eosin, ×4). G, Colonic biopsies from the above patient show crypt architectural distortion and a crypt abscess, consistent with chronic active colitis and suggestive of inflammatory bowel disease (hematoxylin and eosin, ×10). H, Follow-up colonic biopsies taken after cessation of the medication show normal histology (hematoxylin and eosin, ×4). In our experience, this is a rare presentation in the colon, microscopic colitis being more frequent. I, This ARB-exposed patient had prominent crypt apoptosis (arrows), a finding which could be confused with mycophenolate toxicity (hematoxylin and eosin, ×60).

Table 1 Summary of case series and case reports

	No. of patients	Length of olmesartan use before symptoms	HLA DQ2/DR8	Small bowel villous atrophy	IEL	Collagenous sprue	Microscopic colitis	Lymphocytic or collagenous gastritis	Clinical resolution after drug cessation
Rubio-Tapia et al 2012 [1]	22	0.5-7 y (14)[a]	81% (21)	68% TVA 32% PVA	64%	32%	38% (13)	50% (14)	100%
DeGaetani et al 2013 [10]	16	NA	92% (13)	50% TVA 12% STVA 19% PVA 19% NSVA	69%	69%	NA	NA	100% (15)
Theophile et al 2014 [11]	5	NA	NA	40% STVA 40% PVA 20% No VA	40%	NA	NA	NA	100%
Bhat et al 2014 [12]	7	0.5-5 y	NA	29% TVA 14% STVA 57% PVA	100%	NA	100% (1)	NA	100%
Ianiro et al 2014 [13]	3	3 y (1)	0%	67% TVA 33% PVA	0%	NA	NA	NA	100%
Scialom et al 2015 [8]	7	2-10 y	67% (6)	57% TVA 43% STVA	100%	14%	0%	14%	67% (6)
Marthey et al 2014 [6]	36	<1 mo-11.5 y	63% (19)	72% TVA/STVA 17% PVA 11% No VA	68% (28)	8% (26)	19%	NA	92%
Single cases[b]	8	0.5-7 y (5)	43% (7)	63% TVA 12% PVA 25% NSVA	88%	50% (2)	80% (5)	100% (1)	100%
Total	104	<1 mo-11.5 y (70)	70% (69)	67% TVA/STVA 23% PVA 5% NSVA 5% No VA	70% (96)	30% (73)	27% (62)	41% (22)	95% (102)

Abbreviations: IEL, intraepithelial lymphocytosis; NA, not available; NSVA, nonspecified villous atrophy; PVA, partial villous atrophy; STVA, subtotal villous atrophy; TVA, total villous atrophy; VA, villous atrophy.

[a]Values in parenthesis indicate the number of patients evaluated for a given characteristic.

[b]Includes results from Nielsen et al, Stanich et al, Dreifuss et al, Khan et al, Fiorucci et al, de Fonseka et al, Gaur et al, and Heerasing et al [14-21].

3 months after drug cessation showed villous recovery and a decrease in IELs [13]. A series of 3 patients reported from Italy as part of a review manifested typical clinical findings, and all responded dramatically to cessation of olmesartan. Interestingly, the index biopsies had severe villous atrophy, but they lacked significant intraepithelial lymphocytosis [14]. This was also noted in a sizable minority of the patients described by Rubio-Tapia et al [1].

Several isolated case reports of olmesartan-associated enteropathy have been published. Nielsen et al [15] reported a case of collagenous sprue in an individual taking olmesartan who experienced a 20-lb weight loss over a few weeks. Discontinuation of olmesartan because of resolution of hypertension resulted in complete symptomatic and pathologic recovery [15]. The case of a patient requiring total parenteral nutrition with sprue-like histology and lymphocytic colitis was reported by a group from Ohio State University. Total resolution of symptoms was noted just 7 days after cessation of olmesartan [16]. These observations are consistent with our experience, where patients typically start to notice great improvement just days after medication cessation. Other groups from the United States, Australia, and Italy have reported similar cases [17-22]. The latter described lymphocytic gastritis and lymphocytic colitis in addition to the characteristic duodenal findings. Interestingly in this case, lymphocytic colitis had been overlooked at the time of original histopathology review and was only recognized on re-reviewing the case [19]. A suspected case of olmesartan enteropathy has been reported in which the patient had chronic diarrhea but presented in an emergent setting with a colon perforation, which was managed with antibiotics and cessation of olmesartan therapy, after which the patient had a profound recovery. Unfortunately, adequate histologic findings were not provided (reported as "inflammatory changes in the stomach and colon") [23].

2. Epidemiological studies

The incidence of sprue-like enteropathy among olmesartan users has yet to be quantified. However, a group in France recently made efforts toward this end by collecting case reports of angiotensin receptor blocker (ARB)–associated enteropathy from gastroenterologists across the country. In total, 27 medical centers submitted 48 reports. Of these, 40 (83%) had complete data available, and 36 (75%) included biopsies confirming abnormal intestinal histology associated with olmesartan use. Although this study provides some information regarding prevalence, its scope is somewhat limited, as only gastroenterologists were contacted, and it remains likely that due to low awareness of this condition, patients are still being misclassified as having celiac disease or an inflammatory disorder [6]. Another French study used the hospitalization records of 4 546 680 ARB and angiotensin-converting enzyme inhibitor (ACEI) users to assess the risk of enteropathy associated with olmesartan use. The authors determined the incidence of hospitalization for intestinal malabsorption among olmesartan users, ACEI users, and nonolmesartan ARB users. The incidence of hospitalizations for olmesartan users was 2.49 times that of ACEI users and 3.17 times that of other ARB users. The incidence of hospitalizations for other ARB users was 0.78 times that of ACEI users, suggesting that, among ARBs, olmesartan is more likely to be associated with enteropathy. Hospitalizations with a discharge diagnosis of celiac disease were also considered. The incidence of hospitalizations for celiac disease for olmesartan users was 4.39 times that of ACEI users and 4.82 times that of other ARB users. The rate of hospitalizations for other ARB users was 0.91 times that of ACEI users [24]. A recent study at our institution reviewed medication records for patients undergoing endoscopy or colonoscopy for chronic diarrhea and compared the medications to a control group of patients for whom the indication was either heartburn (for endoscopy) or colon cancer screening (for colonoscopy). No significant association between olmesartan use and chronic diarrhea was observed; however, this study was underpowered, as only a small percentage (0.7%-1%) of the study population was taking olmesartan [25]. Further studies are necessary to get a more accurate sense of the frequency of olmesartan-associated enteropathy, particularly in the United States.

3. Disease spectrum

Future studies should also clarify the spectrum of gastrointestinal symptoms and histologic changes associated with olmesartan use, as recent works have introduced the possibility of milder presentations. A report from 2012 described a suspected case of sprue-like enteropathy in a patient taking olmesartan for 3 years [26]. Duodenal biopsy revealed mild villous blunting, increased IELs, and negative celiac serology. However, the patient did not exhibit symptoms typical of enteropathy, such as diarrhea. This suggests that, in addition to severe sprue-like enteropathy, olmesartan use may be associated with a broader range of gastrointestinal pathology [26]. Our recent study suggested that olmesartan can induce more subtle intestinal damage in patients who lack the severe diarrhea characteristic of sprue-like enteropathy. In this study, intestinal biopsies from both olmesartan users and control patients experiencing abdominal pain (but not diarrhea) were retrospectively examined for sprue-like features including architectural abnormalities, increased IELs, and chronic inflammation. Although no single feature was statistically more frequent in either group, the results taken as a whole suggested a trend of sprue-like histologic changes in olmesartan users; specifically, 50% of patients taking olmesartan had 1 characteristic as compared to only 20% of control patients. Whether this milder presentation represents a stage in the ultimate development of severe sprue-like enteropathy or a limited injury remains to be determined [2]. Notably, in the aforementioned French study of ACEI and ARB users, the incidence of hospitalization was also determined with respect to treatment duration. Within the ACEI and olmesartan groups, patients were divided into 3 groups of treatment duration: less than 1 year, 1 to 2 years, and 2+ years. The rate ratio of hospitalization for intestinal malabsorption for olmesartan compared with ACEI was 0.76 for the less than 1 year group, 3.66 for the 1 to 2 years group and 10.65 for the 2+ years group. The rate ratio of hospitalization for celiac disease for olmesartan compared with ACEI was 1.98 for the less than 1 year group, 4.36 for the 1 to 2 years group, and 10.21 for the 2+ years group. Thus, the incidence of enteropathy-related hospitalizations increases markedly as time of exposure to olmesartan increases, suggesting that olmesartan-induced enteropathy may develop slowly [24]. Therefore, future studies are awaited to determine whether olmesartan can induce varying degrees of gastrointestinal damage and, if so, the resultant spectrum of symptoms and histologic findings. The role of olmesartan in the etiology of microscopic colitis also needs to be established.

4. Nonolmesartan ARBs

Other drugs in the class of ARBs have a similar intended mechanism, but it is uncertain to what degree they may be associated with a clinical syndrome or histopathologic changes similar to those observed for olmesartan. A few recent reports have implicated several nonolmesartan ARBs in sprue-like enteropathy. For instance, a case report in which a patient had symptoms and histologic findings quite similar to what has been described above for olmesartan and was found to be taking valsartan. Cessation of valsartan coincided with a complete resolution of symptoms following years of debilitating diarrhea [3]. Two cases of irbesartan-associated enteropathy have also been reported. One patient, a 54-year-old woman, experienced abdominal pain and significant weight loss after taking irbesartan for less than 1 year. Duodenal biopsies demonstrated total villous atrophy, and antibody testing confirmed negative celiac serology. Withdrawal of irbesartan resulted in clinical

remission [6]. A second similar case has also been reported [5]. The possibility of a class effect is further suggested by a case report describing telmisartan-associated enteropathy in a 71-year-old woman who presented with diarrhea and weight loss after 2 months of telmisartan use. Histologic findings revealed villous atrophy, subepithelial collagen deposition, lamina propria inflammation, and intraepithelial lymphocytosis in the terminal ileum. Normal histology and relief of symptoms were achieved within 7 months after drug cessation [4]. Clinical trials of the more recently released ARB, azilsartan, are also worth considering. Although no histopathologic changes have been described, the manufacturer reported that diarrhea was the most common side effect (2% versus 0.5% placebo) observed during clinical trials of 4184 patients [27]. Another trial of the drug also found diarrhea to be an adverse effect (4.2% for 80 mg dose versus 1.3% placebo) [28]. Further studies could elucidate whether diarrhea experienced by patients taking azilsartan is associated with sprue-like histologic changes.

5. Histopathologic differential diagnosis

Based on the histologic features described above, it is clear that the histopathology of ARB enteropathy overlaps with both common and rare etiologies of small intestinal mucosal injury. Although not discussed in the literature thus far, we have observed that most ARB-enteropathy cases exhibit varying degrees of granulocytic infiltration (both neutrophils and eosinophils) and increased crypt apoptosis. This broadens the differential even further, and there is no cardinal finding which can establish the diagnosis of olmesartan-induced injury based solely on histopathology. On the other hand, if one is aware that this entity exists and obtains the relevant history, then the diagnosis is fairly straightforward in most cases. The entities with overlapping histopathologic features are discussed below, and where possible, distinctions are noted (Table 2).

5.1. Celiac disease

For most pathologists, the first consideration when encountering a flat duodenal biopsy is celiac disease, and indeed, up to 15% of patients will carry a diagnosis of seronegative celiac disease [10,29]. Based on personal experience and the published literature, there are some subtle histologic differences which can be observed. It is unusual to see a flat lesion in celiac disease and not be able to detect an appreciable increase in IELs. On the other hand, studies have shown that a sizable proportion of ARB enteropathy patients do not display this feature [1,14]. In addition, ARB enteropathy cases are very frequently associated with increased subepithelial collagen, which is a rare complication of celiac disease [1,10]. Ultimately, seronegativity and ARB use are the most meaningful discriminators between celiac disease and ARB enteropathy.

5.2. Tropical sprue

Tropical sprue is notable for severe intraepithelial lymphocytosis usually without profound villous atrophy, and flat lesions are rare [30]. Collagenous sprue is not generally associated with otherwise typical tropical sprue. As many cases of ARB enteropathy are associated with microscopic colitis, it is not likely that comparison of duodenal and ileal biopsies (often

Table 2 Possible histopathologic differences between ARB enteropathy and other entities

Entity	Histopathologic features	Distinguishing features of ARB-enteropathy
Celiac disease	Intraepithelial lymphocytosis Crypt hyperplasia Villous atrophy	IEL sometimes within, or close to, normal limits Collagen deposition frequent
Tropical sprue	Intraepithelial lymphocytosis, often worse in terminal ileum than duodenum Often preserved architecture	Villi often flat IEL sometimes within, or close to, normal limits Collagen deposition frequent
Autoimmune enteropathy	Variable features—villous atrophy, possible intraepithelial lymphocytosis, loss of goblet cells,loss of Paneth cells	No known histopathologic distinguishing features
Crohn disease	Patchy active inflammation Intraepithelial lymphocytosis Granulomas Variable architectural distortion	Granulomas not characteristic Diffuse involvement Collagen deposition frequent
Mycophenolate toxicity	Typically shows only increased crypt apoptosis; however, some cases may show intraepithelial lymphocytosis and/or villous atrophy	More diffuse and severe villous atrophy More chronic and active inflammation Collagen deposition frequent

Abbreviations: ARB, angiotensin receptor blocker; IEL, intraepithelial lymphocytosis.

helpful in the differential of tropical sprue and celiac disease) would be particularly useful in the distinction of tropical sprue and ARB enteropathy.

5.3. Autoimmune enteropathy

AIE is an autoimmune disorder which causes intractable diarrhea in both children and adults and is, at least in some instances, associated with autoantibodies to intestinal epithelial cells [31]. Histopathologically, it demonstrates villous atrophy, intraepithelial lymphocytosis, chronic and active (acute) inflammation, increased crypt apoptosis (resembling graft-versus-host disease), and sometimes loss of goblet and Paneth cells (which are the target of the autoantibodies) [31]. All of these findings have been described in ARB enteropathy and observed in such cases in our clinical practice [8]. Therefore, the distinction of AIE and ARB enteropathy seems practically impossible without the relevant history (Fig. D-F).

5.4. Inflammatory bowel disease

Both Crohn disease and ulcerative colitis can affect the duodenum in approximately 1/4 to 1/3 of cases [32,33]. We are unaware of granulomas being identified in ARB enteritis, whereas they are seen in variable numbers of Crohn patients (although some studies report finding them only rarely) [32,33]. Thus, if a granuloma is encountered in the duodenum, Crohn disease or an infectious etiology is much more likely than ARB enteritis. Furthermore, although this has not been formally studied, while Crohn disease demonstrates a patchy distribution, ARB enteropathy seems to affect the duodenum more diffusely. Duodenal involvement by ulcerative colitis may be more difficult to distinguish, although, again, collagenous sprue is not typically a feature of upper gastrointestinal involvement by ulcerative colitis. See Fig. G and H.

5.5. Other medications

Other types and classes of drugs can have protean manifestations in the gastrointestinal tract. Medications derived from mycophenolic acid can cause sprue-like changes in the duodenum [10,34]. The most characteristic finding in most cases of mycophenolate toxicity is increased crypt apoptosis (Fig. I). However, intraepithelial lymphocytosis and villous atrophy can also be seen in such cases [34,35].

6. Conclusions

Olmesartan-associated enteropathy is a recently described entity with clinical features including severe diarrhea and weight loss. The mechanism of injury is not well established, but the phenotypic similarity to the entities described above suggests an immune-mediated inflammatory disorder in susceptible individuals. Histopathologic findings include severe (total) intestinal villous atrophy with more variable intraepithelial lymphocytosis, frequently increased subepithelial collagen, and inflammation of lamina propria. Cessation of olmesartan results in complete resolution of both clinical and histologic features. Less frequently, other drugs of the same class have been reported to cause this syndrome. It is also possible that less severe forms of intestinal injury are also associated with olmesartan use. Although we have attempted to provide histopathologic features which may aid in the differential diagnosis, definitive diagnosis requires clinico-pathological correlation, highlighting the importance of effective 2-way communication between pathologists and gastroenterologists. Very rarely can such a small intervention (switching antihypertensive medications) have such a drastic impact on a patient's health, thus, it is important for pathologists, as well as other physicians, gastroenterologists, cardiologists, and primary care, among others, to be aware of the histopathologic changes associated with ARB enteropathy.

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EXHIBIT 5

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NOT FOR PUBLICATION
United States District Court, D. New Jersey.

Sandra GEISS and Robert Geiss h/w, Plaintiffs,
v.
TARGET CORPORATION and/or Target Corporation of Minnesota, John Does 1–5 (fictitious persons) and ABC Corps 1–5 (fictitious corporations), Defendants/Third Party Plaintiff(s),
v.
Virtua Memorial Hospital, Virtua Memorial Hospital—Mt. Holly, Virtua West, John Does 1–10 (names unknown) and ABC Corps 1–10 (names unknown), Third Party Defendant(s).

Civil No. 09–2208 (RBK/KMW).
|
Aug. 30, 2013.

Attorneys and Law Firms

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OPINION

KUGLER, District Judge.

***1** This matter comes before the Court upon the motion of Target Corporation ("Target") for partial summary judgment, pursuant to Federal Rule of Civil Procedure 56, against Sandra and Robert Geiss ("Plaintiffs"). Virtua Memorial Hospital ("Virtua"), a third party defendant in this case, also now moves for summary judgment. For the reasons expressed herein, Target's motion for summary judgment is **DENIED.** However, Virtua's motion for summary judgment is **GRANTED.**

I. FACTS AND PROCEDURAL HISTORY

According to Plaintiffs, this matter arises out of a fall that Plaintiff Sandra Geiss sustained at a Target store in Burlington, New Jersey. Because Plaintiff's medical history and post-fall treatment are relevant to the conflicting theories of causation advanced by both parties, the Court will provide a detailed background to this case. Although the Court presents a composite of facts from Plaintiffs, Target, and Virtua, the Court will construe all facts in the light most favorable to the non-moving parties, as it must at this stage in the litigation.

In January 2006, Plaintiff underwent knee replacement surgery in which her right knee joint was removed and replaced with a prosthetic component. Target's Mot. Summ. J., Ex. P–1 at 1. Plaintiff alleges that on July 25, 2007, she tripped over an uneven rug while passing through the entrance of the Burlington, NJ Target store, landing on her stomach and knees. *Id.*, Ex. B at 2; Target's Statement of Undisputed Material Facts ("SUMF"), ¶ 2. Plaintiff did not experience immediate pain on the day of her fall, but days later developed increasing pain in her right knee and required a cane and walker to ambulate. *Id.*, Ex. T at 33–40. On August 2, 2012, Plaintiff visited her primary care physician, Dr. Chatyrka, complaining of right knee pain. Target's SUMF, ¶ 3. Dr. Chatyrka determined that Plaintiff was suffering from sciatica and recommended that she obtain an X-ray of her right knee. Target's Mot. Summ. J., Ex. C. The X-ray indicated that the prosthetic components were properly positioned and undamaged, but also revealed a fluid collection of unknown origin. *Id.*, Ex. D.

On August 17, 2012, Dr. Schoifet, the orthopedic surgeon who performed Plaintiff's knee replacement in 2006, examined Plaintiff's knee. *Id.*, Ex. E. Dr. Schoifet noted Plaintiff's complaints of increasing knee pain, but found that Plaintiff had no instability in her knee and confirmed that the X-ray demonstrated good positioning of the prosthetic components. *Id.*; Target's SUMF, ¶ 5–6. He ultimately concluded that Plaintiff suffered a right knee contusion as a result of her fall. *Id.*

On August 29, 2012, Plaintiff Sandra Geiss presented to Virtual Memorial Hospital complaining of "back pain, leg pain, numbness, pain radiating from back into legs and extreme pain when ambulating." Pls.' Supplemental Statement of Disputed Material Facts ("SDMF"), ¶ 7. A few hours after Plaintiff's arrival, tests revealed that Plaintiff had an elevated white blood cell count, elevated

blood pressure, high blood sugar, and a high temperature. Target's Mot. Summ. J. at 4; *see also* Ex. F at 6–8. Soon thereafter, Plaintiff was diagnosed with hypoxia and pneumonia. *Id.*, Ex. F at 9. Plaintiff was admitted to the hospital, and then to the Intensive Care Unit, where she was intubated. *Id.*, Ex. I at 2. Blood cultures also revealed that Plaintiff had MSSA (Methicillin–Sensitive Staphylococcus Aureus), a bacterial infection. *Id.* Plaintiff spent some time in the ICU in order to receive treatment for her various ailments and to stabilize her condition. *See* Pls.' Opp'n, Ex. A at 42–43. Dr. Lee does not recall exactly how long Plaintiff remained in the ICU. [1] *Id.* at 42–43.

***2** Much of the controversy in this case surrounds an "event" which allegedly occurred during Plaintiff's hospitalization. On September 25, 2007, an X-ray of Plaintiff's right knee revealed that her previously intact right knee prosthesis had subluxed (dislocated) by 3cm. Target's Mot. Summ. J., Ex. J. Plaintiff underwent emergency repair surgery on September 26, 2007, while her immune system was still compromised from the treatment of her other ailments. *Id.*, Ex. Q at 99–100. Despite the repair, Plaintiff subsequently developed an infection in her right knee requiring further treatment. Target's SUMF, ¶ 32. The infection persisted, which required doctors to remove the prosthesis and insert an antibiotic spacer. *Id.* at ¶ 33. Ultimately, Dr. Schoifet had to perform a "right knee arthrodesis," or fusion of Plaintiff's right knee. *Id.* at ¶ 34. Plaintiff's knee fusion has caused her significant pain, led to difficulty walking, and altered the range of activities in which she can participate. Dep. of Sandra Geiss at 90–94.

Although the subluxation was discovered on September 25, 2007, Plaintiff has no memory as to when or how it occurred. Target's Mot. Summ. J., Ex. T at 56–57. According to Plaintiff's expert, Dr. Gleimer, this subluxation occurred at some point while Plaintiff was hospitalized, but he cannot pinpoint a specific event, place or date. *Id.*, Ex. P–1 at 3. He does note, however, that the prosthetic is inherently stable and would not sublux on its own. *Id.* This confusion is enhanced due to a number of missing medical records. Specifically, Virtua cannot locate progress notes from August 29, 2007 to September 14, 2007, physician orders from September 4, 2007 to September 17, 2007, medical administration records from September 4, 2007 to September 19, 2007, and flow records from September 14, 2007, September 18, 2007 and October 3, 2007. Target's SUMF, ¶ 35. The Custodian of Records for Virtua, Jennfier Raio, attributes the loss of the records to human error. Virtua's Mot. Summ. J., Ex. D at 64–65.

On the basis of these events, Plaintiffs filed suit against Target on March 26, 2009 in the Superior Court of New Jersey, Burlington County. In the Complaint, Plaintiffs assert claims against Target for negligence and loss of consortium on behalf of Plaintiff Robert Geiss. Target was served on April 6, 2009. Within one month, Target properly moved the matter to this Court. On July 29, 2010, Target impleaded Virtua as a third party defendant in the case. In the Third Party Complaint, Target contends that Plaintiff's knee subluxation constitutes a superseding, intervening cause and that any injuries resulting therefrom are due solely to Virtua's negligence. Target seeks contribution and indemnification from Virtua for any damages for which Target may be liable to Plaintiffs in the underlying suit. Target's Third Party Compl., ¶ 11. Target also claims that it has been prejudiced by Virtua's failure to preserve all of Plaintiff's medical records and asserts a tort action for careless, negligent, and/or intentional spoliation of evidence, seeking contribution and/or indemnification as a remedy. *Id.* at 3–4.

***3** Both Virtua and Target now move for summary judgment. Target argues that Plaintiff's knee subluxation was neither actually nor proximately caused by Target's negligence. Target also contends that the expert opinion causally relating Plaintiff's fall at Target to her subsequent hospitalization should be barred as a net opinion. In its motion for judgment on the Third–Party Complaint, Virtua argues that neither party has adduced evidence supporting a prima facie case of negligence. Accordingly, Virtua asserts that there is no issue of material fact and that the hospital is entitled to judgment as a matter of law based on the current record.

II. STANDARD OF REVIEW

The court should grant a motion for summary judgment when the moving party "shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(a). An issue is "material" to the dispute if it could alter the outcome, and a dispute of a material fact is "genuine" if "a reasonable jury could return a verdict for the non-moving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986); *Matsushida Elec. Indus. Co., Ltd. v. Zenith Radio*

Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986) ("Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.' ") (quoting *First National Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 289, 88 S.Ct. 1575, 20 L.Ed.2d 569 (1968)). In deciding whether there is any genuine issue for trial, the court is not to weigh evidence or decide issues of fact. *Anderson*, 477 U.S. at 248. Because fact and credibility determinations are for the jury, the non-moving party's evidence is to be believed and ambiguities construed in her favor. *Id.* at 255; *Matsushida*, 475 U.S. at 587.

Although the movant bears the burden of demonstrating that there is no genuine issue of material fact, the non-movant likewise must present more than mere allegations or denials to successfully oppose summary judgment. *Anderson*, 477 U.S. at 256. The nonmoving party must at least present probative evidence from which jury might return a verdict in his favor. *Id.* at 257. The movant is entitled to summary judgment where the non-moving party fails to "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986).

III. DISCUSSION & ANALYIS

Target's Third Party Complaint seeks contribution and indemnification from Virtua for any liability that Target may face in Plantiffs' underlying action. If Target's motion is granted, Virtua's motion for summary judgment would be rendered moot. Therefore, it is prudent for the Court to first address Target's motion for summary judgment.

A. Target's Motion for Partial Summary Judgment

Target moves for summary judgment based on Plaintiffs' alleged failure to establish causation. Target argues that its alleged negligence was neither the actual nor proximate cause of Plaintiff's knee subluxation and the complications resulting therefrom. Target further posits that Plaintiff's knee subluxation was a superseding intervening cause which severs the causal chain of liability. Target also seeks to bar Dr. Gleimer's conclusion that "all hospitalizations subsequent to July 25, 2007 related to Ms. Geiss' knee, back or related infection or problems were caused by the fall at Target." *See* Target's Mot. Summ. J. at 31. Target argues that Dr. Gleimer's statement is a "net opinion," which is unsubstantiated by objective evidence. *Id.* The Court will address these arguments in reverse order, beginning with Target's challenge to Plaintiffs' expert.

a. Sufficiency of Expert Testimony

***4** Target challenges Dr. Gleimer's conclusion that all hospitalizations subsequent to July 25, 2007 are causally related to Plaintiff's fall at Target, arguing that it is a "net opinion" that is unsupported by the factual record. Admissibility of expert testimony is governed by Rule 702, which was amended in 2000 to reflect the Supreme Court decision in *Daubert*. The Rule provides as follows:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed.R.Evid. 702. This rule requires a court to act as a "gatekeeper" to ensure that expert testimony is both relevant and reliable. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir.2008). Rule 702 has a " 'liberal policy of admissibility.' " *Id.* (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir.1997)). The burden of showing expert testimony is admissible, once challenged, lies with the offering party. *See Kannankeril*, 128 F.3d at 807.

To be admissible, expert testimony must satisfy three requirements under Rule 702: 1) the witness must be an expert (i.e., must be qualified); 2) the expert must testify about matters requiring scientific, technical, or specialized knowledge (i.e., must be reliable); and 3) the expert's testimony must assist the trier of fact (i.e, must fit). *Id.* at 806 (citing *In re Paoli R.R. Yard PCB Litig. (Paoli II)*, 35 F.3d 717, 742 (3d Cir.1994)); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir.2000) (stating three requirements are qualifications, reliability, and fit). An expert is qualified if

he " 'possesses specialized expertise.' " *Pineda*, 520 F.3d at 244 (quoting *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir.2003)). The qualification requirement is liberally construed. *Id*.

A reliable opinion is "based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Paoli II*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 589). The focus of the reliability inquiry is on the expert's principles and methodology, not on his conclusions. *Daubert*, 509 U.S. at 595. In determining reliability, a court may look to several non-exhaustive factors, including:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non judicial uses to which the method has been put.

*5 *Elcock*, 233 F.3d at 745–46 (quoting *Paoli II*, 35 F.3d at 742 n. 8). Finally, an opinion fits a particular case (and thus helps the trier of fact) when there is a " 'connection between the scientific research or test result to be presented and particular disputed factual issues in the case.' " *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir.2000) (quoting *Paoli II*, 35 F.3d at 743). Fit is an issue of relevance and simply means that scientific validity of the method or principles applies to the issues at hand. *U.S. v. Ford*, 481 F.3d 215, 220 n. 6 (3d Cir.2007).

Target has not raised a proper *Daubert* challenge. Target does not challenge Dr. Gleimer's expertise, the reliability of his methodology, or the relevance of his opinion to this particular case. Target merely challenges the reliability of his conclusions. This is not the "inquiry envisioned by Rule 702." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). As the Supreme Court cautioned, the overarching subject of a challenge under Rule 702 is "the scientific validity and thus the evidentiary relevance and reliability —of the principles that underlie a proposed submission." *Id.* Consequently, the Court's focus "must be solely on principles and methodology, not on the conclusions that they generate." *Id.*

Even construing Target's motion as a challenge to the reliability of Dr. Gleimer's methodology, Target has not raised any justification for barring his opinions. Target first argues that Dr. Gleimer "elected to disregard the medical evidence" and failed to explain how Plaintiff's presentation to the emergency room could have been caused by her fall. Target Mot. Summ. J. at 30. Target also finds significant that Dr. Gleimer cannot state exactly how and when the knee dislocation occurred, but attributes the dislocation to "some event/injury while in the hospital." *Id.* Target further contends that Dr. Gleimer failed to explicitly state that his opinions are based upon a reasonable degree of medical probability or certainty. *Id.* at 31. However, Dr. Gleimer did explain at length his reasons for reaching this conclusion. *See* Dr. Gleimer Dep. at 42–45. The balance of Target's arguments may be properly raised on cross-examination, not on a Rule 702 challenge. Therefore, the Court will deny Target's request to bar Dr. Gleimer's opinions.

b. Negligence

In order to establish negligence under the laws of New Jersey, a plaintiff must establish: (1) a duty of care owed to Plaintiff, (2) a breach of that duty, (3) actual and proximate causation, and (4) damages. *Jersey Cent. Power & Light Co. v. Melcar Utility Co.*, 212 N.J. 576, 594 (2013). Target only challenges Plaintiffs' ability to establish the third prong—actual and proximate causation.

i. Proximate Causation

Target argues that Plaintiff cannot establish that Target's negligence was the proximate cause of her knee subluxation. Target accords little weight to Dr. Gleimer's opinion that an "event" occurred during her hospitalization, but argues that even accepting this conclusion, "it is not foreseeable [that] any treatment for this alleged injury would cause a stable, intact knee prosthetic to dislocate, even if that treatment was negligently administered." Target's Mot. Summ. J. at 27.

Target also highlights that Plaintiff's own expert "does not state [that] plaintiff was receiving treatment for her back when the knee dislocation occurred, or that the dislocation of plaintiff's was a foreseeable consequence of such treatment." *Id.* However, none of these arguments justify summary judgment.

*6 Under well-established principles of tort law, "a tortfeasor is generally held answerable for the injuries which result in the ordinary course of events from his negligence and it is generally sufficient if his negligent conduct was a substantial factor in bringing about the injuries." *Rappaport v. Nichols*, 31 N.J. 188, 156 A.2d 1, 9 (N.J.1959). Therefore, to be considered a proximate cause, "conduct need only be a cause which sets off a foreseeable sequence of consequences, unbroken by any superseding cause, and which is a substantial factor in producing the particular injury." *Bendar v. Rosen*, 247 N.J.Super. 219, 588 A.2d 1264, 1269 (N.J.Super.Ct.App.Div.1991) (quoting *Scafidi*, 574 A.2d at 398). The New Jersey Supreme Court has been clear that "[p]roximate cause is a factual issue, to be resolved by the jury after appropriate instruction by the trial court." *Scafidi v. Seiler*, 119 N.J. 93, 574 A.2d 398, 402 (N.J.1990).

Contrary to Target's arguments, Plaintiffs have identified a triable issue of fact as to causation. First, Plaintiffs have offered ample evidence that Plaintiff's visit to the emergency room was spurred by severe back and knee pain. In her deposition, Plaintiff states that she had her husband call an ambulance "because of the excruciating pain she was experiencing in her knee and back." Pls.' SDMF, ¶ 3. Dr. Gleimer opines, and some of the emergency records indicate, that Plaintiff presented to the hospital with complaints of severe left leg pain, back pain, and ambulatory pain. *Id.*, Ex. F; Ex. P–2 at 1. The records also note that Plaintiff complained of "pain to lower back" and that Plaintiff "ambulate[d] slowly without assistance." *Id.* at 6–7.

Although, as Plaintiff concedes, the reasons for her actual admission remain less certain, Plaintiffs have also produced sufficient evidence on this point to survive summary judgment. Plaintiffs' expert, Dr. Gleimer, concluded that there were multiple reasons for Plaintiff's admission and observed that she was treated almost exclusively for her low back pain and sciatica. Pls.' Opp'n at 5(citing Gleimer Dep. at 44–45). Dr. Gleimer notes that these painkillers can also suppress respiration. *Id.* Dr. Gleimer also highlights that Virtua's Admission Record lists back pain as "one of the conditions chiefly responsible for Ms. Geiss' admission to Virtua." *Id.* (citing Gleimer Dep. at 45–46). Dr. Lee, the admitting doctor on the date in question, also testified that Plaintiff was admitted, at least in part, for "low back pain." *Id.* (citing Lee Dep. at 29). Thus, Plaintiffs have produced adequate evidence for a jury to find that Target's initial negligence was a proximate cause of her knee subluxation.

ii. Actual Causation

Target also argues that Plaintiff's fall was not the actual cause of her knee subluxation. Essentially, Target argues that because an x-ray confirmed that Plaintiff's prosthetic knee was in place after her initial fall and because Dr. Gleimer cannot state with certainty how or when the knee dislocation occurred, Target cannot be the actual cause of her subsequent injury. This argument fundamentally misconstrues the meaning of "actual cause." Actual cause serves as an "important corollary to the proximate cause rule." *See Dawson v. Bunker Hill Plaza Associates*, 289 N.J.Super. 309, 326, 673 A.2d 847 (App.Div.1996). In order to impose liability, a plaintiff must also establish that defendant's negligent conduct was "a substantial factor in bringing about harm to another." *Id.* An actor's conduct is not a substantial factor, "if [the injury] would have been sustained even if the actor had not been negligent.' " *Id.*

*7 Taking the evidence in the light most favorable to the non-moving party, Plaintiffs have established that Target's conduct was an actual cause of the knee subluxation. Target incorrectly focuses on whether the fall was the direct cause of Plaintiff's injury. However, the law is clear that Target can be liable, "even where there are 'other intervening causes which were foreseeable or were normal incidents of the risk created.' " *Camp v. Jiffy Lube No. 114*, 309 N.J.Super. 305, 309–10, 706 A.2d 1193 (App.Div.1998). Target has not provided any valid basis for summary judgment. Therefore, Target's motion for summary judgment is DENIED.

B. Virtua's Motion for Summary Judgment

Virtua has also moved for summary judgment on Target's Third–Party Complaint against the hospital. Virtua argues that "[n]o party has factually established a prima facie claim against Virtua for negligence." Virtua Mot. Summ. J. at 5. Virtua also contends that to the extent that

Target's claim against Virtua alleges medical malpractice, expert testimony is required to establish a deviation from accepted medical standards. *Id.* at 4, 706 A.2d 1193. Target responds with a number of arguments, none of which are presented with particular lucidity. Target first argues that it need not produce expert testimony because the "common knowledge" exception applies. Target then contends that Virtua's negligent spoliation of evidence entitles Target to an adverse inference. Target also raises the doctrine of "unclean hands" to thwart Virtua's motion for summary judgment. Finally, Target attempts to assert a claim for fraudulent concealment. The Court will address these arguments in turn.

a. Negligence

It is axiomatic that "the mere showing of an incident causing the injury sued upon is not alone sufficient to authorize the finding of an incident of negligence." *Long v. Landy*, 35 N.J. 44, 54, 171 A.2d 1 (1961). As a third-party plaintiff, Target bears the burden of demonstrating the existence of negligence. *See Buckelew v. Grossbard*, 87 N.J. 512, 435 A.2d 1150, 1157 (N.J.1981) ("We start with the basic proposition that ordinarily negligence must be proved and will never be presumed, that indeed there is a presumption against it, and that the burden of proving negligence is on the plaintiff"). Negligence may only be inferred from proven facts and circumstances and cannot be based on speculation or conjecture. *Long*, 35 N.J. at 54, 171 A.2d 1.

Target largely ignores these well-settled principles and attempts to survive summary judgment without providing any competent evidence of Virtua's negligence. Target argues that "the 'event' presumably occurred as a result of the carelessness, negligence, and/or gross negligence of Virtua." Target's Opp'n at 9. However, the law is clear that negligence "will never be presumed." *Buckelew*, 435 A.2d at 1157. Target first attempts to surmount this obstacle by invoking the "common knowledge" exception. According to Target, the common knowledge exception is applicable "where a lay person using ordinary understanding and experience is sufficient to determine a defendant's negligence without the benefit of expert testimony." Target's Opp'n (citing *Bender v. Walgreen Eastern Co. ., Inc.*, 399 N.J.Super. 584, 590, 945 A.2d 120 (N.J.Super.Ct.App.Div.2008)). Target previously raised this same exception in its opposition to Virtua's prior motion to dismiss in relation to the Affidavit of Merit requirement. The Court rejected its application then and will do so again.[2] *See* Doc. No. 30 at 7. Moreover, even if the Court did apply the common knowledge exception, it would not obviate Target's obligation to establish negligence. It merely alters the proofs upon which a plaintiff may rely to demonstrate a deviation from the standard of care.

**8 In addition to raising the common knowledge exception, Target makes two ill-fated attempts to establish a duty by Virtua. Target Mot. Summ. J. at 11. Target appears to argue that Virtua breached some duty to Target by failing to preserve evidence, which prejudiced Target. However, Target has not identified the source of such a duty. To the extent that Target relies on a common law duty to preserve evidence, Target has not established any of the required elements. The duty to preserve evidence only arises when there is pending or likely litigation between two parties, knowledge of this fact by the alleged spoliator, evidence relevant to the litigation, and the foreseeability that the opposing party would be prejudiced by the disposal of this evidence. *Cockerline v. Menendez*, 411 N.J.Super. 596, 620, 988 A.2d 575 (App.Div.2010). Target also argues that Virtua violated a statutory duty, imposed by N.J. 13:35–6.5, by failing to maintain complete and accurate records.[3] However, the statute does not give rise to a cause of action. *See Proske v. St. Barnabas Med. Ctr.*, 313 N.J.Super. 311, 318–19, 712 A.2d 1207 (App.Div.1998) (finding that N.J.S.A. 26:8–5 does not create a statutory cause of action and that "violation of the statute did not have a causal relation to the physical injury suffered"). Therefore, Target has not alleged any fact, much less provided competent evidence, of Virtua's negligence.[4]

b. Fraudulent Concealment of Evidence

Target also asserts a claim for fraudulent concealment of evidence against Virtua.[5] In order to prove this tort, a plaintiff must demonstrate that: (1) the defendant in the fraudulent concealment action had a legal obligation to disclose evidence in connection with *existing* or *pending* litigation, (2) the evidence was material to the litigation, (3) the plaintiff could not have reasonably obtained the evidence elsewhere, (4) the defendant *intentionally* withheld, altered, or destroyed evidence with purpose to disrupt litigation, (5) Plaintiff was damaged by having to rely on an incomplete record that did not contain the evidence defendant concealed. (emphasis added) *Rosenblit v. Zimmerman*, 166 N.J. 391, 406–07, 766 A.2d 749 (2001).

Target has not established these elements. Target has not provided any evidence that the missing records may have been material to this litigation. Target has not even established that Virtua intentionally withheld the missing entries. Even under the favorable standard of review on summary judgment, Target's claims cannot survive.

In the Third–Party Complaint, Target alleged claims for negligence and what this Court will construe as fraudulent concealment of evidence against Virtua. However, Target has failed to "make a showing sufficient to establish the existence of an element essential to [its] case." *Celotex*, 477 U.S. at 322. Therefore, the Court will grant Virtua's motion for summary judgment. [6]

IV. CONCLUSION

For the foregoing reasons, Target's Motion for Partial Summary Judgment is DENIED. Virtua's motion for summary judgment is GRANTED. An appropriate order shall issue today.

ORDER

*9 **THIS MATTER** having come before the Court on the motions of Virtua Memorial Hospital ("Virtua") and Target Corporation ("Target") for summary judgment, pursuant to Federal Rule of Civil Procedure 56, and the Court having considered the moving papers and attached documents, and the responses thereto, and for the reasons expressed in the Opinion issued this date;

IT IS HEREBY ORDERED that Target's motion for summary judgment is **DENIED.**

IT IS HEREBY FURTHER ORDERED that Virtua's motion for summary judgment on Target's Third Party Complaint is **GRANTED.**

All Citations

Not Reported in F.Supp.2d, 2013 WL 4675377

Footnotes

1 Plaintiff remained in the hospital until she was discharged on October 11, 2007. Target's SUMF, ¶ 24.

2 In the August 2, 2011 Opinion and Order, the Court stated: "Target has not demonstrated that its claim turns on common knowledge. Target alleges only that 'something' happened while Mrs. Geiss was at Virtua that caused her injuries. Target does not allege that an obvious error by Virtua or its employees caused Mrs. Geiss' injuries. Rather, Target acknowledges that it does not know the exact cause of her injuries. Because Mrs. Geiss received medical treatment, her injuries may have resulted from negligent medical care that requires expert testimony to prove."

3 Virtua notes that Target relies on the wrong statutory provision provision. According to Virtua, NJAC 13:35–6.5 is an administrative code and is not applicable to institutions. Virtua instead posits that NJSA 26:8–5 is the appropriate statutory provision mandating the maintenance of records.

4 Virtua also urges the Court to apply the doctrine of "unclean hands" and deny Virtua's motion for summary judgment. This doctrine "gives expression to the equitable principle that a court should not grant relief to one who is a wrongdoer with respect to the subject matter in the suit." *Faustin v. Lewis*, 85 N.J. 507, 427 A.2d 1105, 1107 (N.J.1981). As with every other argument in Target's opposition, Target has not demonstrated how this doctrine would be applicable. Although it is unfortunate that Virtua could not provide Plaintiff's complete medical record in discovery, Target has not provided any evidence of "wrongdoing with respect to the subject matter in the suit." Jennifer Raio testified that despite their best efforts in searching, her team had not been able to uncover the missing records. Jennifer Raio Dep., Target's Opp'n, Ex. D, 33–34. Moreover, Target has not produced any evidence or testimony linking Virtua's failure to maintain records to Plaintiff's actual injury.

5 The Third Party Complaint does not explicitly articulate a claim for fraudulent concealment, but it does contain allegations of spoliation of evidence. As Target states, spoliation of evidence claims are recognized as the tort of fraudulent concealment. *See Rosenblit v. Zimmerman*, 166 N.J. 391, 406, 766 A.2d 749 (2001).

6 Target also seeks an adverse inference jury instruction based on Virtua's alleged spoliation of evidence. Even if the Court were denying Virtua's motion, the Court would not be inclined to address jury instruction requests on a motion for summary judgment.

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EXHIBIT 6

2017 WL 1352860
Only the Westlaw citation is currently available.
United States District Court,
E.D. Louisiana.

IN RE: XARELTO (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION
This Document Relates to: All Cases

MDL NO. 2592

Signed 04/12/2017

Filed 04/13/2017

ORDER & REASONS

SECTION L

ELDON E. FALLON, UNITED STATES DISTRICT JUDGE

***1** Before the Court are several motions to exclude certain areas of anticipated testimony of various expert witnesses for the Boudreaux and Orr bellwether trials. Having considered the parties arguments and the applicable law, the Court now issues this order and reasons.

I. *DAUBERT* LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Rule 702 is in effect a codification of the United States Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). In *Daubert*, the Supreme Court held that trial courts should serve as gatekeepers for expert testimony and should not admit such testimony without first determining that the testimony is both "reliable" and "relevant." *Id.* at 589.

The trial court is the gatekeeper of scientific evidence. *Daubert*, 509 U.S. at 596. It has a special obligation to ensure that any and all expert testimony meets these standards. *Id.* Accordingly, it must make a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and whether the reasoning or methodology can be properly applied to the facts in issue. *Id.* at 592–93. In making this assessment, the trial court need not take the expert's word for it. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997). Instead, when expert testimony is speculative or lacks scientific validity, trial courts are encouraged to exclude it. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 279 (5th Cir. 1998).

In satisfying its "gatekeeper" duty, the Court will look at the qualifications of the experts and the methodology used in reaching their opinions and will not attempt to determine the accuracy of the conclusion reached by the expert. The validity or correctness of the conclusions is a determination to be made by the fact finder after the *Daubert* analysis.

Scientific testimony is reliable only if "the reasoning or methodology underlying the testimony is scientifically valid," meaning that such testimony is based on recognized methodology and supported by appropriate validation based on what is known. *Daubert*, 509 U.S. at 592–93. In *Daubert*, the Supreme Court set forth a non-exclusive list of factors to consider in determining the scientific reliability of expert testimony. *Id.* at 593–95. In the context of the present case, these factors are: (1) whether the theory has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error; (4) whether standards and controls exist and have been maintained with respect to the technique; and (5) the general acceptance of the methodology in the scientific community. *Id.* Whether some or all of these factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 138 (1999).

In addition to the five factors laid out in *Daubert*, a trial court may consider additional factors to assess the scientific reliability of expert testimony. *Black v. Food Lion, Inc.*, 171 F.3d 308, 312 (5th Cir. 1999). These factors may include: (1) whether the expert's opinion is based on incomplete or inaccurate data; (2) whether the expert has identified the specific mechanism by which the drug supposedly causes the alleged disease; (3) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (4) whether the expert has adequately accounted for alternative explanations; and (5) whether the expert proposes to testify about matters growing directly out of research he

or she has conducted independent of the litigation. *See, e.g., id.* at 313; *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278–79 (5th Cir. 1998); *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1114 (5th Cir. 1991); *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 678 (W.D. Tex. 2002). Scientific testimony is relevant only if the expert's reasoning or methodology can be properly applied to the facts at issue, meaning there is an appropriate fit between the scientific testimony and the specific facts of the case. *Daubert*, 509 U.S. at 593. Scientific evidence is irrelevant, however, when there is too great an analytical gap between the data and the opinion proffered. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

*2 The party seeking to introduce the expert testimony bears the burden of demonstrating that the testimony is both relevant and reliable. *Moore*, 151 F.3d at 275–76. The requirement of reliability does not strictly bind an expert within the proffered field of expertise; an expert may also testify concerning related applications of his or her background. *Slatten, LLC v. Royal Caribbean Cruises Ltd.*, No. 13-673, 2014 WL 5393341, at *2 (E.D. La. Oct. 23, 2014) (citing *Wheeler v. John Deere Co.*, 935 F. 2d 1090, 1100 (10th Cir. 1991)). The focus is not on the result or conclusion, but on the methodology. *Moore*, 151 F.3d at 275–76. The proponent need not prove that the expert's testimony is correct, but must prove by a preponderance of the evidence that the expert's methodology was proper. *Id.* Both the Plaintiffs and Defendants have various experts in this case. The Court will address each of the motions in turn.

A. Defendants' Motion to Exclude Certain Opinions of Dr. Laura Plunkett

Before the Court is Defendant's Motion to Exclude Certain opinions of Dr. Laura M. Plunkett, Ph.D., DABT (R. Doc. 5108). Defendants seek to limit Dr. Plunkett's testimony regarding Xarelto labeling and the state of mind or knowledge of both Defendants and the FDA. Plaintiffs disagree, arguing that Dr. Plunkett's testimony is well within her expertise and pointing out that most courts which have considered her qualifications and methodology have found her "eminently qualified to testify about drug pharmacology, general causation, regulatory matters and the adequacy of labels for both prescription and non-prescription drugs." Plaintiffs contend that in arguing that Dr. Plunkett is not qualified in regulatory or labeling, Defendants are arguing that she is not qualified to do exactly what she does when consulting for pharmaceutical companies.

Dr. Plunkett is a pharmacologist and toxicologist who has substantial experience as an expert witness. She is a Diplomate of the American Board of Toxicology and a registered patent agent. She is neither a medical doctor nor a regulatory agent for the FDA, but has extensive experience consulting and advising as to regulatory matters, including label content. The Defendants do not dispute Dr. Plunkett's qualifications, and this Court finds she is well-qualified by her experience and education.

The Court further finds that Dr. Plunkett's opinions are based on her review of Defendants' and the FDA's statements and documents, as well as medical journals and reports. Defendants' arguments go to the witness's conclusions, not her methodology or qualifications, and accordingly may be dealt with by cross-examination at trial.

Accordingly, Defendants' Motion (R. Doc. 5108) is **DENIED**.

B. Defendants' Motion to Exclude Certain Opinions of Dr. David Kessler

Before the Court is Defendants' Motion to exclude portions of Dr. David Kessler's expert report that lack a reliable foundation and that are inappropriate testimony for an expert witness. (R. Doc. 5111). Plaintiffs oppose the Motion, arguing that Defendants take pieces of Dr. Kessler's opinion out of context in making their failing arguments. Plaintiffs further contend Dr. Kessler is uniquely qualified to offer opinions on the conduct of pharmaceutical companies.

Dr. David Kessler, M.D., is a medical doctor, the former Commissioner of the Food and Drug Administration, a professor of food and drug law, and an advisor to pharmaceutical companies. He has testified before Congress on multiple occasions and has published numerous articles in legal, medical, and scientific journals on the federal regulation of drugs and medical devises as well as the intersection of federal regulation and state law. Currently, Dr. Kessler is a senior advisor to a global private equity firm that owns pharmaceutical and biomedical companies and serves on the boards of two pharmaceutical companies. He advises corporates on the proper standard of care under both state and federal law.

*3 The Court finds Dr. Kessler is well qualified by virtue of his education and prior positions to render expert opinions. He bases his opinions on medical literature, federal regulations, and his experience. He uses appropriate methodology in forming his opinions. The objections Defendants argue in their motion are better reserved for cross-examination at trial. Accordingly, Defendants' Motion (R. Doc. 5111) is **DENIED**.

C. Defendants' Motion to Exclude Certain Opinions of Dr. Suzanne Parisian

Before the Court is Defendants' Motion to exclude certain portions of Dr. Suzanne Parisian's expert report. (R. Doc. 5112). Specifically, they argue her recitation of Xarelto's regulatory history is not proper expert witness testimony, and that she is unqualified and uses poor methodology in giving her opinions on medical or regulatory causation, foreign regulatory issues, and what information is important to patients or doctors. Plaintiffs oppose the motion, arguing Dr. Parisian is highly qualified and is one of the few people who specializes in the complexities of FDA regulation. They aver Dr. Parisian will assist the jury in understanding the regulatory requirements applicable to pharmaceutical manufacturers and drug labeling within the context of the FDA.

The Court finds that Dr. Parisian is qualified by virtue of education and experience and she uses sound methodology in reaching her conclusions. The thrust of the Defendants' objections seems to be that they are concerned the witness may assume an advocate role at trial. If Dr. Parisian assumes an advocate role at trial, the Court will address it at that time. For the time being, however, Defendants' Motion (R. Doc. 5112) is **DENIED**.

D. Defendants' Motions Regarding Unapproved Dosage and Monitoring Regimens and the 20-second PT cutoff guideline

Before the Court are Defendants' Motions to Exclude Expert Opinions and Testimony Regarding Unapproved Dosage and Monitoring Regimens (R. Doc. 5113) and to Preclude Opinions and Testimony Regarding Plaintiffs' Experts' 20-second PT cutoff guideline. (R. Doc. 5114).

1. Dosage and Monitoring Regimens

Defendants aver that Plaintiffs expert witnesses opine that patients' risk of bleeding could be reduced if doctors monitored the concentration or anticoagulant effect of Xarelto, and if the FDA-approved dosages were changed. In approving Xarelto, the FDA approved a fixed-dose regimen of 20 milligrams once a day. Plaintiffs oppose Defendants' motion, arguing that the motion is procedurally improper. FRE 702 is meant to exclude or allow particular witnesses based on their qualifications and methodology; it is not meant to exclude or allow entire issues. Daubert motions are meant to address methodology and qualifications; this motion does not do so. The Defendants do not question any particular expert's specialized knowledge or methodology, preventing the court from meaningfully evaluating the issues and experts. Further, Plaintiffs contend that Defendants take quotes and opinions entirely out of context, making Plaintiffs' experts appear to say or testify to something different than that to which they are actually testifying.

2. 20-second PT cutoff guideline

Several of Plaintiffs' Expert Witnesses opine that if physicians monitored the concentration of anticoagulation effect of Xarelto in their patients—particularly by using prothrombin time ("PT") using a Neoplastin reagent—bleeding risk would be reduced. PT is a non-specific method to measure the amount of time it takes a person on an anticoagulant to clot. Defendants seek to preclude any expert testimony regarding the 20-second PT cutoff discussed by several of Plaintiffs' experts. They construe Plaintiffs' argument as: any patient with a PT level higher than a certain point should be switched to an alternate anticoagulant or be prescribed a lower, non-FDA approved dose of Xarelto. This argument, Defendants aver, is not reliable and does not fit the facts of the Orr and Boudreaux bellwether cases and is therefore not relevant to the litigation.

*4 Plaintiffs contend that the PT tests are factually significant to this case. They aver that the Bellwether Plaintiffs must have had a high Neoplastin PT result because they had a significant bleeding episode. Relying on FDA and Defendant-supported data, a high Neoplastin PT result and a bleeding episode are

correlated. The possible use of a Neoplastin PT test to these Bellwether Plaintiffs should not be disputed. Further, Plaintiffs contend that Dr. Rinder relied on peer-reviewed literature to compare PT values. His report was neither late nor unscientific, and he produced the chart he used in his determination. Plaintiffs argue Dr. Rinder never claims to be converting the PT numbers, just making an indirect comparison and approximation based on the chart. His methods, Plaintiffs contend, are sound.

3. Analysis

The Court finds that the opinions Defendants seek to exclude go to the crux of Plaintiffs' theory of the case. Dosing and monitoring (including the 20-second PT cutoff) are relevant to Plaintiffs' theory that Xarelto was defectively designed and its label lacked relevant information or directions regarding its safe use. Because of Xarelto's short half-life and the variability in patients, some patients will retain more Xarelto in their system and will be subject to a greater bleeding risk. Xarelto's dosing scheme and the availability of monitoring bear on the individual risk to each plaintiff taking Xarelto. Plaintiffs contend that proper usage requires testing or monitoring to ascertain the appropriate dosage. They argue that this was known or should have been known to Defendants and the label should contain information and instructions or directions as to proper use. Plaintiffs point to various journals and studies supporting their position. Without judging the accuracy of this conclusion, the methodology supporting the Plaintiffs' argument is appropriate. Defendants' quarrel is with the witnesses' conclusions and not their methodology. Accordingly, Defendants' Motions (R. Docs. 5113, 5114) are **DENIED**.

E. Plaintiffs' Motion to Exclude Certain Opinions of Dr. James Reiffel

Before the Court is Plaintiffs' Motion to Preclude Dr. James A. Reiffel, M.D., from testifying regarding attorney advertising and earlier cancer detection from anticoagulant-elated bleeds. (R. Doc. 5116). Defendants oppose, arguing his testimony is reliable and relevant. Further, they contend that limiting their ability to make arguments about attorney advertising would be prejudicial because Plaintiffs plan to discuss Defendants' Xarelto advertisements. Further, the statements regarding early detection of diseases such as cancer are relevant and reliable as part of the entire risk-benefit analysis of Xarelto. The entire analysis, they aver, must be weighed by a jury when ascertaining whether or not Xarelto was defectively designed.

This Court finds that Dr. Reiffel's testimony regarding the effect of attorney advertising is not relevant or reliable and is therefore excluded. However, such testimony may be offered as rebuttal testimony if the issue is raised on direct examination at trial. For example, if there is evidence that the patient in question avoided taking Xarelto or abruptly stopped taking Xarelto due to attorney advertising, then this ruling may have to be modified.

This Court also finds Dr. Reiffel's testimony regarding early cancer detection to be irrelevant in this case, as cancer was not an issue for either Plaintiff. Further, there is no evidence that Xarelto is routinely prescribed to screen for cancer. Accordingly, such testimony is also excluded. If this becomes an issue during the trial, then this ruling will be modified.

For the aforementioned reasons, **IT IS ORDERED** that Plaintiffs' Motion (R. Doc. 5116) is **GRANTED**.

F. Defendants' Motion to Exclude Certain Opinions of Dr. Nathaniel Winstead

*5 Before the Court is Defendants' Motion to exclude part of Dr. Nathaniel Winstead's expert report, specifically his opinion that Xarelto can cause internal bleeding absent any underlying pathology because his methodology does not meet the requirement under *Daubert* and its progeny. (R. Doc. 5120). Dr. Winstead is a case-specific expert in the *Boudreaux* bellwether case. Plaintiffs oppose the motion, arguing that Dr. Winstead is qualified to provide expert testimony regarding Xarelto's ability to cause internal bleeding through "systemic toxicity," and point out that Dr. Winstead's main opinion, which Defendants don't oppose, is that Xarelto is the most probable cause of Plaintiff Boudreaux's gastrointestinal bleed. Further, Plaintiffs argue that rather than a mere hypothesis, Dr. Winstead's opinion is supported by his clinical experience, peer-reviewed studies, and other sources including Xarelto's label.

Dr. Nathaniel Winstead, MD, is a general gastroenterologist and hepatologist with clinical experience with Warfarin, and is double-board-certified in gastroenterology and internal medicine. In researching for

and writing his expert report, Dr. Winstead attests that he used the same methods he uses to evaluate and treat his patients. From 2008-2013, Dr. Winstead was the Director of Gastroenterology Research and the Medical Director of the Inflammatory Bowel Disease Center at Ochsner. He was the principal investigator or sub-investigator in multiple clinical trials for various drug manufacturers, including Defendant Janssen. As a medical doctor, Dr. Winstead sees approximately 100-200 GI bleeds a year and has regularly concluded that certain bleeds are a result of anticoagulants themselves, including through systemic toxicity. In preparing for this case, Dr. Winstead reviewed Plaintiff Boudreaux's medical records, depositions of other witnesses, various iterations of Xarelto's label, and numerous Xarelto studies.

The Court finds Dr. Winstead is qualified by virtue of his training and experience. He reaches his conclusion that NOACs, and specifically Xarelto, can cause bleeding without underlying pathology through his experience, the presence of the drug in Plaintiff's stool, peer reviewed literature, and Xarelto's label. Defendants may cross-examine Dr. Winstead on these issues at trial in an attempt to establish the frailty of the basis of his conclusions, but excluding them at this time is inappropriate.

For the aforementioned reasons, **IT IS ORDERED** that Defendants' Motion (R. Doc. 5120) is **DENIED**.

G. Plaintiffs' Motion to Preclude Speculative Testimony About Potential Outcomes from Other Anticoagulants

Before the Court is Plaintiffs' Motion to Preclude Speculative Testimony About Potential Outcomes from Other Anticoagulants which asks the Court to prevent Drs. Smith, Piazza, and Branch from testifying about what might have happened to the bellwether Plaintiffs if they had taken a different anticoagulant. (R. Doc. 5121). Defendants contend that Plaintiffs misconstrue their experts' testimony, arguing that their opinions are relevant to rebut Plaintiffs' claim that Xarelto is not as reliable as other drugs and that there is a safer alternative. To not allow this testimony, Defendants contend, would be prejudicial to their case and their ability to defend themselves against Plaintiffs' theories.

One of Plaintiffs' theories in this case is that Xarelto was defectively designed. Under the Louisiana Products Liability Act, this requires showing that a safer alternative design existed. The evidence presented here by Defendants' experts, Drs. Smith, Piazza, and Branch, attempts to rebut the claim of a safer alternative design and accordingly is admissible on rebuttal of Plaintiffs' defective design theory. The Doctors' opinions are based on their experience and training, are relevant, and are based on proper methodology. At trial, Plaintiffs may cross-examine these witnesses as to the validity of their conclusions, but excluding their testimony at this stage would be improper. The Court, however, may revisit this issue at trial if the evidence so warrants.

*6 For the aforementioned reasons, **IT IS ORDERED** that Plaintiffs' Motion (R. Doc. 5121) is **DENIED**.

H. Plaintiffs' Motion to Exclude Certain Opinions of Dr. J. Michael Gaziano

Before the Court is Plaintiffs' Motion to preclude certain testimony from Dr. J. Michael Gaziano, MD, MPH, regarding the adequacy of Xarelto's label, Xarelto's dosing scheme, and the Time in Therapeutic Range (TTR) for warfarin as compared to Xarelto. (R. Doc. 5127). Defendants disagree, arguing that Plaintiffs mischaracterize Dr. Gaziano's opinions and aver that he is more than qualified to offer this testimony based on his extensive experience, training as a cardiologist and epidemiologist, his clinical trial experience, his research, and his review of medical literature on Xarelto and other anticoagulants.

Dr. J. Michael Gaziano, MD, MPH, has been a physician for 30 years. He received his MD from Yale and his MPH with a concentration in cardio-epidemiology from Harvard. He is a cardiologist in Boston where he teaches and sees patients including those who require anticoagulant therapy. Dr. Gaziano is a professor at Harvard Medical School and an adjunct professor at Boston University Medical School, and is board certified in cardiovascular disease. Throughout his career he has participated in and directed clinical trials and has also published various books and articles focusing on cardiology.

The Court finds Dr. Gaziano is well qualified by his education and experience, and that his opinions are based on his experience and his review of test data and literature. Dr. Gaziano's opinions are based on proper methodology and are relevant to the issues in dispute in this case. Further, the thrust of Plaintiffs' concerns lie

in Dr. Gaziano's conclusions, not his methodology or qualifications. Accordingly, Plaintiffs concerns are better dealt with on cross-examination at trial.

For the aforementioned reasons, **IT IS ORDERED** that Plaintiffs' Motion (R. Doc. 5127) is **DENIED**.

I. Plaintiffs' Motion to Preclude Speculative Testimony About Potential Outcomes from Other Anticoagulants

Before the Court is Plaintiffs' second Motion to Preclude Speculative Testimony About Potential Outcomes from Other Anticoagulants, which asks the Court to prevent Drs. Boniol, Johnson, Kahn, Eiswirth, and Peacock from testifying about what might have happened to the bellwether Plaintiffs if they had taken a different anticoagulant. (R. Doc. 5399). They argue these opinions were not subject to peer review or tested, are without standards controlling their opinion, and are not generally accepted within the scientific community. They also argue such opinions are irrelevant and run a high risk of undue prejudice. Adopting their opposition to the first motion to exclude speculative testimony, Defendants contend that Plaintiffs misconstrue their experts' testimony, arguing that their opinions are relevant to rebut Plaintiffs' claim that Xarelto is not as reliable as other drugs and that there is a safer alternative. To not allow this testimony, Defendants contend, would be prejudicial to their case and their ability to defend themselves against Plaintiffs' theories. Defendants further argue that Plaintiffs own expert witnesses agree that they cannot rule out the possibility of a bleeding event on another anticoagulant. Further, Defendants contend that all of the doctors base their opinions on their education, training and expertise and on extensive review of relevant studies, literature, and medical records.

*7 One of Plaintiffs' arguments is that there is a safer alternative to Xarelto. The testimony of these expert witnesses seeks to rebut that theory. Further, the testimony goes toward Defendants' theory that Xarelto was an appropriate drug for Plaintiffs to take. This Court finds the testimony is proper as the experts are well-qualified and their testimony is relevant and based on proper methodology. Accordingly, Plaintiffs' Motion (R. Doc. 5399) is **DENIED**.

J. Plaintiffs' Motion to Exclude Certain Opinions of Drs. Scott Boniol and William Franklin Peacock IV

Before the Court is Plaintiffs' Motion to exclude the section of Dr. Scott Boniol's and Dr. William Franklin Peacock IV's expert reports that opine on the earlier detection of cancer and other diseases due to anticoagulant-related bleeding events. (R. Doc. 5401). Defendants oppose the motion, arguing the statements regarding early detection of diseases such as cancer are relevant and reliable as part of the entire risk-benefit analysis of Xarelto. The entire analysis, they aver, must be weighed by a jury when ascertaining whether or not Xarelto was defectively designed.

Dr. Scott Boniol, MD, is a hematologist and oncologist. Dr. William Franklin Peacock IV, MD, FACEP, is a board-certified emergency medicine physician and a fellow of the American Colleges of Emergency Physicians and Cardiology. Plaintiffs do not dispute either doctor's expert credentials, and the Court finds they are qualified by virtue of their education and experience to offer expert testimony.

The Court finds the testimony of Drs. Boniol and Peacock regarding early cancer detection to be irrelevant in this case, as cancer was not an issue for either Plaintiff. Further, there is no evidence that Xarelto is routinely prescribed to screen for cancer. Accordingly, such testimony is excluded. If this becomes an issue during the trial, then this ruling will be modified). Accordingly, Plaintiffs' motion (R. Doc. 5401) is **GRANTED**.

K. Plaintiffs' Motion to Exclude Certain Opinions of Dr. Scott Boniol

Before the Court is Plaintiffs' Motion to exclude the section of Dr. Scott Boniol's expert report that gives his opinion about the effects of attorney advertising because they are subjective, unscientific, unreliable, and unduly prejudicial. (R. Doc. 5404). Defendants oppose, arguing his testimony is reliable and relevant. Further, they contend that limiting their ability to make arguments about attorney advertising would be prejudicial because Plaintiffs plan to discuss Defendants' Xarelto advertisements.

Dr. Scott Boniol, MD, is a hematologist and oncologist. Plaintiffs do not dispute his expert credentials, and the Court finds he is qualified by nature of his education and experience to offer expert testimony. Further, his opinions regarding Xarelto are based on experience, data, and on medical journals. However, the Court finds Dr. Boniol's

commentary on attorney advertising and the effect of that advertising on patients is argumentative and are excluded under F.R.E. 401 and 403. Dr. Boniol may discuss the danger to patients who prematurely stop taking Xarelto, but may not relate that danger to attorney advertising. However, testimony regarding attorney advertising may be offered as rebuttal testimony if the issue is raised on direct examination at trial. If there is evidence that the patient in question avoided taking Xarelto or abruptly stopped taking Xarelto due to attorney advertising, then this ruling may have to be modified.

*8 Consistent with the aforementioned reasons, **IT IS ORDERED** that Plaintiffs' Motion (R. Doc. 5404) is **DENIED IN PART** and **GRANTED IN PART**.

II. CONCLUSION

For the aforementioned reasons, **IT IS ORDERED** that Defendants' Motion to exclude certain opinions of Dr. Laura Plunkett (R. Doc. 5108) is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion to exclude certain opinions of Dr. David Kessler (R. Doc. 5111) is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion to exclude certain opinions of Dr. Suzanne Parisian (R. Doc. 5112) is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion to exclude expert opinions and testimony regarding unapproved dosage and monitoring regimens (R. Doc. 5113) is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion to preclude opinions and testimony regarding Plaintiffs' experts' 20-second PT cutoff guideline (R. Doc. 5114) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to exclude certain opinions of Dr. James Reiffel (R. Doc. 5116) is **DENIED**.

IT IS FURTHER ORDERED that Defendants' Motion to exclude certain opinions of Dr. Nathaniel Winstead (R. Doc. 5120) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to preclude speculative testimony about potential outcomes from other anticoagulants (R. Doc. 5121) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to exclude certain opinions of Dr. J. Michael Gaziano (R. Doc. 5127) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to preclude speculative testimony about potential outcomes from other anticoagulants (R. Doc. 5399) is **DENIED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to exclude certain opinions of Drs. Scott Boniol and William Franklin Peacock IV (R. Doc. 5401) is **GRANTED**.

IT IS FURTHER ORDERED that Plaintiffs' Motion to exclude certain opinions of Dr. Scott Boniol (R. Doc. 5404) is **GRANTED IN PART** and **DENIED IN PART**.

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